DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/27/09 has been entered.

2. Applicant's arguments filed 10/27/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 15-16 and 27 are pending in this office action.

5. The information disclosure statement (IDS) submitted on 11/11/09 is acknowledged and has been reviewed.

6. Claims 15-16 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hidaka et al. (US Patent 5,972,976) in view of Goodman and Gilman (1996) as made of record in Paper No. 20090427 and as follows. It should be noted that Ragaz is withdrawn from the rejection as the claims no longer recite the use of radiation/ radiotherapy.

Applicant argues that "claim 27 is directed to a method for treating at least one malignant tumor selected from blood cancer, leukemia, human colon adenocarcinoma .....administering a therapeutically effective amount of E) -4- [2- [2- [N-acetyl-N- [(p-methoxyphenyl) sulfonyl] amino] phenyl] ethenyl] pyridine 1 – oxide ….wherein the therapeutically effective amount of E) -4- [2- [2- [N-acetyl-N- [(p- methoxyphenyl) sulfonyl] amino] phenyl] ethenyl] pyridine 1 – oxide with cisplatin gives a synergistic inhibitory effect". Applicant further argues that the "T/C value is an indicator that shows how long survival times of animals of a treated group are extended compare to those of a control group".

In response after careful consideration, Applicant's argument is found not persuasive. Page 6 and 7 of the response displays a graph showing that "a survival advantage is considered to be synergistic, not additive, when a survival advantage value obtained in a combined administration of two drugs is larger than a sum of each survival advantage value obtained in each single administration of the two drugs". Based solely on Applicant's own definition the assertion that the combination yields synergism is therefore found not persuasive. The combination of the dosages simultaneously gave a T/C value of about 240, which is less than an additive value of

about 300 (i.e., based on the Table provided by Applicant on page 6 of the response). Again, it is merely an additive effect and does not show synergism. The data simply does not indicate synergism.

Summary of the rejection

Hidaka et al teach a pharmaceutical composition for treating malignant tumor (see col. 1 lines 13+) with a compound of formula I wherein the compound is E) -4- [2- [2- [N-acetyl-N- [(p- methoxyphenyl)sulfonyl] amino] phenyl] ethenyl] pyridine 1 – oxide.

Although Hidaka fails to teach combinations with other known anticancer agents such as cisplatin, Goodman and Gilman teach that the antitumor agents cisplatin and carboplatin may be combined with other anticancer drugs for the treatment of cancers, such as breast, ovary and lung (see pages 1229 and 1230) wherein Goodman and Gilman specifically teach "drugs are generally more effective in combination and may be synergistic…"

Therefore one of ordinary skill in the art would have been motivated to combine a known anticancer drug employed in the treatment of breast cancer with the newly found drug of Hidaka that is capable of treating the same type of disease via a different mechanism because Goodman and Gilman teach the combination of anticancer drugs, which such may result in a synergistic effect. Accordingly, in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), the court held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order form a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
12/10/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649